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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/715,482	11/19/2003	Naveen Arora	2761-0169P	3751

2292 7590 07/09/2009

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EXAMINER	
FORD, VANESSA L	

ART UNIT	PAPER NUMBER
1645	

NOTIFICATION DATE	DELIVERY MODE
07/09/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

Office Action Summary	Application No.	Applicant(s)	
	10/715,482	ARORA ET AL.	
	Examiner	Art Unit	
	VANESSA L. FORD	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 June 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-8,36 and 37* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-8, 36 and 37* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *19 November 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's amendment filed June 17, 2009 has been entered. Claims 1, 3-8 and 36-37 are under examination.

Rejections Maintained

2 The rejection of claims 1, 3-8 and 36-37 under 35 U.S.C. 102(a) as anticipated by Bijli et al *(Clin. Exp. Allergy, January 2003)* is maintained for the reasons set forth on pages 2-6 paragraph 3 of the Final Office Action.

The rejection is reiterated below:

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The rejection was on the grounds that Bijli et al teach a 67kDa protein purified from *Imperata cylindrica* (page 65). Bijli et al teach a protein that is stable at room temperature (see Abstract). Bijli et al teach a 67kDa protein binds IgE (page 68). Claims limitations such as “hydrophobic in nature”, “resistant to trypsin”, “has no proteolytic activity”, “inhibits proteolytic cleavage of protective antigen (PA) of *B. anthracis* in a dose dependent manner”, “is devoid of any carbohydrate moiety”, “wherein the range of about 25-20 ng completely inhibits the cleavage of the protective antigen of *B. anthracis* by trypsin” wherein protein in the range of about 15-5 ng completely inhibits the cleavage of the protective antigen of *B. anthracis* by trypsin”, “wherein the protein in the

range of about 25 ng to 11, 000 ng is effective in inhibiting the anthrax activity" and "wherein the protein in the range of about 50 to 10, 000 ng is effective in inhibiting anthrax activity" would be inherent in the teachings of the prior art.

Since the Office does not have the facilities for examining and comparing applicant's protein with the protein of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed product and the product of the prior art (i.e., that the protein of the prior art does not possess the same material structural and functional characteristics of the claimed protein). See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

Applicant's Arguments

Applicant urges that *Thorpe* relates to questions of obviousness and not anticipation. Applicant urges that SDS gel is well known in the art to denature the protein chain and to abolish biological activity of the protein. Applicant urges that there is no procedure disclosed by Bijli, 2003 for obtaining any protein having its normal conformation. Applicant urges that EACA which is a protease inhibitor reagent that is used to stabilize proteins against degradation in protein purification methods. EACA is not a technique for protein purification. Applicant urges that no where in Bijli, 2003 that teaches that the protein is "isolated". Applicant urges that the band is observed at the relevant molecular weight. Applicant urges that Western blot is a method used for identification/detection of protein. Applicant urges that proteins are visualized using Western blot and not particularly purified. Applicant urges that the Lowry assay is only a technique for estimating the amount of total protein in a sample. Applicant urges that Bijli et al 2003 analyzed a crude extract that contains many proteins having molecular weights between 12-110 kDa as shown in figure 1 of the paper. Applicant urges that the Examiner should consider that the function of any particular proteins within the mixture at 67 kDa is not determined and disclosed in the Bijli 2002 reference.

Examiner's Response to Applicant's Arguments

Applicant's arguments filed June 17, 2009 have been fully considered but they are not persuasive.

Bijli et al, 2003 teach an isolated 67 kDa protein extract from *Imperata cylindrica* using EACA and a standard SDS-PAGE gel was used to show protein profiles (see the Abstract and Figure 2). Bijli et al, 2003 teach an isolated protein because the protein is analyzed by SDS-PAGE. It is noteworthy to point out that Bijli et al, 2003 makes reference to a 67 kDa protein from *Imperata cylindrical* in the Introduction section on page 65 of Bijli et al.

It should be remembered that the term "isolate" is defined as separating something from something else. The 67kDa protein was extracted from dried pollens (page 66). The 67 kDa protein was removed from the dried pollen. Bijli, 2003 further teaches that the extract used to perform SDS-PAGE gels. Figure 2 of the Bijli 2003, shows a 67 kDa stable allergen. Thus, the 67 kDa protein is isolated. The 67 kDa protein disclosed in Figure 2 is not a mixture of proteins.

To address Applicant's comments regarding *Thorpe*, it should be noted that *Thorpe* refers to anticipation as well as obviousness since *Thorpe* recites:

> The products of the prior art reference appear to be *the same or an obvious or analogous variant* of the product claimed by the applicant because they appear to possess the same or similar functional characteristics, i.e. an immunogenic composition and a vaccine comprising a purified polypeptide. The purification or production of a product by a particular process does not impart *novelty or unobviousness* to a product when the same product is taught by the prior art. This is particularly true when properties of the product are not changed by the process in an unexpected manner. See In re Thorpe, 227 USPO 964 (CAFC 1985); In re Marosi, 218 USPO 289, 29222-293 (CAFC 1983); In re Brown, 173 USPO 685 (CCPA 1972).

To address comments regarding Western blot or Lowry assay, these are merely procedures that the protein was subjected to. However, as stated above, the 67 kDa protein was extracted and isolated by SDS page. The SDS page is established that the protein has a molecular weight of 67 kDa. Applicant has not established the protein of the prior art and the claimed protein are patentably distinct. Applicant has not submitted any evidence to point to the differences between the claimed protein and the protein of the prior art. Since the protein of the prior art and the claimed protein are the same they would necessarily possess all of the same biological activities as the claimed protein.

To address Applicant's comment regarding function it should be noted that the protein of the prior art is the same as the protein of the claimed invention. The MPEP 2112.01 states that " "*Products of identical chemical composition can not have mutually exclusive properties." a chemical composition and its properties are inseparable*. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990) (Applicant argued that the claimed composition was a pressure sensitive adhesive containing a tacky polymer while the product of the reference was hard and abrasion resistant. "The Board correctly found that the virtual identity of monomers and procedures sufficed to support a prima facie case of unpatentability of Spada's polymerlatexes for lack of novelty.").

Bijli et al, 2003 anticipate the claimed invention.

In view of all of the above, this rejection is maintained.

3. The rejection of claims 1, 3-8 and 36-37 under 35 U.S.C. 102(b) as anticipated by Bijli et al *(Journal of Immunological Methods 260 (Feb. 2002, 91-96)* is maintained for the reasons set forth on pages 9-12, paragraph 5 of the Final Office Action.

The rejection is reiterated below:

The rejection was on the grounds that Bijli et al teach a 67kDa protein purified from *Imperata cylindrica* that binds IgE (page 93, Figures 1 (a)-(c)). Bijli et al teach a protein that is stable at room temperature (page 92). Claims limitations such as "hydrophobic in nature", "resistant to trypsin", "has no proteolytic activity", "inhibits proteolytic cleavage of protective antigen (PA) of *B. anthracis* in a dose dependent manner" and "is devoid of any carbohydrate moiety", wherein the range of about 25-20 ng completely inhibits the cleavage of the protective antigen of *B. anthracis* by trypsin" "wherein protein in the range of about 15-5 ng completely inhibits the cleavage of the protective antigen of *B. anthracis* by trypsin", "wherein the protein in the range of about 25 ng to 11, 000 ng is effective in inhibiting the anthrax activity" and "wherein the protein in the range of about 50 to 10, 000 ng is effective in inhibiting anthrax activity" would be inherent in the teachings of the prior art.

Since the Office does not have the facilities for examining and comparing applicant's protein with the protein of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed product and the product of the prior art (i.e., that the protein of the prior art does not possess the same material structural and functional characteristics of the claimed protein). See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

Applicant's Arguments

Applicant urges that at page 32, column 1 of Bijli 2002 has only estimated the amount of the protein of the crude extract and not of the purified or isolated protein, by the method of Lowry et al. Applicant urges that the 67 kDa SDS-PAGE separated band is a mixture of proteins and not a single protein. Applicant urges that the Examiner should consider that the function of any particular proteins within the mixture at 67 kDa is not determined and disclosed in the Bijli 2002 reference. Applicant urges that one of

ordinary skill in the art who reads these references would consider that the various biological activities and biochemical properties (i), (ii) to (viii) recited in claim 1 for isolated protein of the invention are unexpected (as Examiner asserts is required for patentability under *In re Thorpe* and others).

Examiner's Response to Applicant's Arguments

Applicant's arguments filed June 17, 2009 have been fully considered but they are not persuasive.

Bijli et al, 2002 teach an isolated 67 kDa protein extract from *Imperata cylindrica* and a standard SDS-PAGE gel was used to show protein profiles (see the Abstract and Figure 2). Bijli et al, 2002 teach an isolated protein because the protein is analyzed by SDS-PAGE. It is noteworthy to point out that Bijli et al, 2002 makes reference to a 67 kDa protein from *Imperata cylindrical*. See page 93 of Bijli et al 2002.

It should be remembered that the term "isolate" is defined as separating something from something else. The 67kDa protein was extracted from dried pollens (page 66). Therefore, the 67 kDa protein was removed from the dried pollen. Bijli, 2002 further teaches that the extract used to perform SDS-PAGE gels. Figure 1 of the Bijli 2002, shows a 67 kDa stable allergen. The prior art teaches that the 67-kDa protein has been extracted and isolated on SDS gel and is not a mixture of proteins. See page 93.

To address Applicant's comments regarding *Thorpe,* it should be noted that Thorpe refers to anticipation as well as obviousness since *Thorpe* recites:

The products of the prior art reference appear to be *the same or an obvious or analogous variant* of the product claimed by the applicant because they appear to possess the same or similar functional characteristics, i.e. an immunogenic composition and a vaccine comprising a purified polypeptide. The purification or production of a product by a particular process does not impart *novelty or unobviousness* to a product when the same product is taught by the prior art. This is particularly true when properties of the product are not changed by the process in an unexpected manner. See In re Thorpe, 227 USPO 964 (CAFC 1985); In re Marosi, 218 USPO 289, 29222-293 (CAFC 1983); In re Brown, 173 USPO 685 (CCPA 1972).

To address comments regarding Lowry assay, these are merely procedures that the protein was subjected to. However, as stated above, the 67 kDa protein was extracted and isolated by SDS page. The SDS page is established that the protein has a molecular weight of 67 kDa. Applicant has not established the protein of the prior art and the claimed protein are patentably distinct. Applicant has not submitted any evidence to point to the differences between the claimed protein and the protein of the prior art. Since the protein of the prior art and the claimed protein are the same they would necessarily possess all of the same biological activities as the claimed protein.

To address Applicant's comment regarding function it should be noted that the protein of the prior art is the same as the protein of the claimed invention. The MPEP 2112.01 states that " "*Products of identical chemical composition can not have mutually exclusive properties." a chemical composition and its properties are inseparable*. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990) (Applicant argued that the claimed composition was a pressure sensitive adhesive containing a tacky polymer while the product of the reference was hard and abrasion resistant. "The Board correctly found

that the virtual identity of monomers and procedures sufficed to support a prima facie case of unpatentability of Spada's polymerlatexes for lack of novelty.").

Bijli et al, 2002 anticipate the claimed invention.

In view of all of the above, this rejection is maintained.

Status of Claims

4. No claims allowed.

Conclusion

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to VANESSA L. FORD whose telephone number is (571)272-0857. The examiner can normally be reached on 9 am- 6 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Mondesi can be reached on (571) 272-0756. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Vanessa L. Ford/
Examiner, Art Unit 1645
July 2, 2009